Faulding
A World of Health

Faulding Pharmaceutical Co.
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AMENDMENT TO CITIZEN PETITION

January 12, 2000

Dockets Management Branch
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Amendment to Docket No. 99P-2252/CP1
Suitability Petition – Pamidronate Disodium Injection
3 mg/mL. 6 mg/mL, 9 mg/mL

Dear Madam/Sir:

Faulding Pharmaceutical Company has been advised that it must address the Final Rule: Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients before final action will be taken on the above referenced suitability petition. While in disagreement with FDA's new policy involving pediatric labeling as applied to the approvability of Suitability Petitions for abbreviated new drug applications, Faulding Pharmaceutical is nevertheless submitting information in support of a waiver for pediatric studies to their Suitability Petition Docket No. 99P-2252/CP1. In accord with 21 CFR 314.55(c) FDA may grant full or partial waiver of the study requirements on its own initiative or at the request of the applicant. Faulding Pharmaceutical Company hereby requests a waiver for the following reasons:

1. The product, Pamidronate Disodium Injection (3mg/mL, 6 mg/mL, and 9 mg/mL) does not truly reflect a change in dosage form at point of administration of the drug product to the patient and will, therefore, not change/increase in any meaningful way the use of this product in the pediatric patient population. The change from a lyophilized powder to a solution provides a convenience to the pharmacist/hospital only.

2. Faulding also evaluated the prevalence of the two disease states, Paget's disease and hypercalcemia in malignancy, in the pediatric population (children from birth to 16 years of age) by conducting an exhaustive search of the available literature in the United States. Based on this research, it does not appear that the prevalence of either disease state meets the general guide for a "substantial number" of pediatric patients which the Final Rule defines as 50,000 pediatric patients.

99P-2252

SUP1

3. The results of this search indicated that the pediatric prevalence of either Paget's disease of bone or hypercalcemia of malignancy, despite substantial variation in epidemiological data, is sufficiently low that identifying adequate patients to enroll in a clinical study would present a significant challenge. To identify patients and implement a proper study could potentially take several years due to the apparent low incidence of these disease states. Therefore, evaluation of the literature indicates that necessary studies are impossible or highly impractical because the number of patients is small and would also be geographically dispersed.

We believe that information provided in this amendment satisfies all apparent outstanding issues related to this petition. We are confident that approval of our petition will now move forward speedily especially since the agency itself communicated to Faulding Pharmaceutical Co. already on December 6, 1999 that pediatric studies would not be required.

Sincerely,
Faulding Pharmaceutical Co.

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs

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